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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,276	01/02/2004	Sebastiano Scarampi	033292-004	7478

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
08/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/751,276	SCARAMPI ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/22/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, request for RCE and IDS, all filed 06/22/2009.

Claims 1, 37-40 previously presented. Claims 41-43 are currently added.

Claims 1, 37-43 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/22/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 41 recites "composition for topical or transdermal administration **consisting of**: (i) nicotine, caffeine or hydrocortisone; and (ii) Gilsonite oil". This is a new matter rejection because no where applicants disclosed composition consisting only of the two claimed elements. The published application, paragraph [0019], states: " In still another of the composition aspects, the present invention provides a composition for topical or transdermal administration with enhanced penetration comprising **Gilsonite oil and a bioactive agent formulated with a penetration enhancing system comprising a Gilsonite oil and a pharmaceutically acceptable carrier,** such as a conventional oil, gel, cream, ointment, lotion, adhesive, polymer, paste, or spray that may optionally contain one or more pharmaceutically acceptable additives selected from the group consisting of excipients, preservatives, antioxidants, fragrances, emulsifiers, dyes, anti-irritants, and additional penetration enhancers. **The Gilsonite oil-bioactive agent component and the Gilsonite oil-carrier component can each be formulated as described above, then these two components can be mixed or formulated in a weight ratio between about 1:100 and about 100:1, preferably about 10:90 to about 90:10 and more preferably about 20:80 to about 80:20.** Accordingly, the composition disclosed by

applicant comprising Gilsonite oil, carrier and bioactive agent, and not consisting of Gilsonite oil and bioactive agent, as instantly claimed by claim 41.

Additionally, the newly added claims 42 and 43 introduced new matter that is not described in the specification as originally filed. New claim 42 recites: "about 10 to 90 wt % Gilsonite oil" and claim 43 recites "about 20 to 80 wt % Gilsonite oil". Recourse to the specification, and paragraphs [0015] and [0017] in particular that applicants are referring to for support, no support was found to this range of Gilsonite oil to the bioactive agent. In paragraphs [0018] of the published application applicants disclosed that: "Gilsonite oil component is present in at least about 0.1% by weight, preferably about 1% to about 80 %, and more preferably about 2 % to about 50 %." Nowhere applicant disclosed the instantly claimed ranges by claims 42 and 43. At set forth, according to paragraph [0019] of the specification, the ratio of 10:90 or 90:10, or 20:80 and 80:20 is disclosed as the ratio between the combination of Gilsonite oil and carrier to the bioactive agent, and not the ratio of Gilsonite oil only to the bioactive agent as recited by the claims.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The term "major proportion" in the claim is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant disclosed range of Gilsonite oil in the composition of at least 0.1%, and preferably between 0.1-80%, and more preferably between 2 and 50%. In view of the disclosed range, and in absence of definition for the term "major proportion", any range within the disclosed range is considered "major proportion".

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orlowski (CA 2,001,688) in view of Friedman et al. (US 7,074,392).

Currently amended claim 1 recites a composition for topical or transdermal administration consisting essentially of: (i) nicotine, caffeine or hydrocortisone; and (ii) Gilsonite oil, and wherein Gilsonite oil is the major proportion ingredient. Since claims are read in light of the specification, and since applicants disclosed at least 0.1% of Gilsonite oil in the composition, then the term "major proportion" will read on any range more than 0.1%. Claim 41 recites a composition for topical or transdermal administration consisting of: (i) nicotine, caffeine or hydrocortisone; and (ii) Gilsonite oil.

Orlowski teaches topical composition for treating human nails comprising 6.25% Gilsonite, mineral oil carrier that reads on excipients and enhancers, preservative, and 3% of soybeans that reads on the bioactive agent and enhancers (page 3, 1st paragraph; page 5, 3rd full paragraph; page 6, 1st paragraph; page 8, 2nd and 4th

paragraphs). Gilsonite oil is a component of the Gilsonite, and Orlowski teaches composition comprising Gilsonite and mineral oil carrier. Therefore, some of the Gilsonite, if not all, will inevitably dissolve in the mineral oil carrier present in the composition releasing Gilsonite oil. Gilsonite inevitably dissolves in hydrocarbon solvent (mineral oil) because compounds and their properties are inseparable. Therefore, the composition taught by the reference contains Gilsonite oil. Orlowski teaches the composition further comprising antibacterial and antifungal agents (page 3; page 5, last paragraph; page 6, 3rd paragraph).

The expression "consisting essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte*, 337 F 2d 870, 143 USPQ 256 (CCPA 1964).

Although Orlowski suggested bioactive agents including antibacterial agent in the composition applied to the nails, however, does not explicitly teach hydrocortisone, nicotine, or caffeine as instantly claimed by claims 1 and 41.

Friedman teaches sustained release nail treating composition comprising antibacterial agents and antipsoriatic agent, with hydrocortisone is preferred

antipsoriatic agent in an amount of 0.1-10% (abstract; col.3, lines 36-39; col.4, lines 46-50; col.14, lines 45-49). The composition is suitable to treat nail and surrounding tissues and it reduces the unwanted side effects caused by high concentration of the antimicrobial agents (col.3, lines 24-28).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition for treating human nails comprising Gilsonite and antimicrobial agent as taught by Orlowski, and further add hydrocortisone to the antimicrobial agent or replace antimicrobial agent with hydrocortisone taught by Friedman according to the condition to be treated. One would have been motivated to do so because Friedman teaches that antimicrobial agents can be administered with hydrocortisone to the nails and further teaches that hydrocortisone is one of the preferred active agents to treat psoriasis of the nails and surrounding tissues and composition comprising hydrocortisone reduces the unwanted side effects caused by high concentration of the antimicrobial agents. One would reasonably expected formulating topical composition for treating human nails comprising Gilsonite and antimicrobial agent and/or hydrocortisone that successfully treats the nail and surrounding tissues without any unwanted side effects.

10. Claims 37-40, 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orlowski (CA 2,001,688) in view of Friedman (US 7,074,392) and further in view of Forrest (US Patent No. 1,573,765, current USPTO form 892).

The combined teaching of Orlowski and Friedman are previously discussed as set forth in this office action.

Orlowski however does not specifically teach the viscosity and the specific gravity of Gilsonite oil as instantly claimed by claims 37 and 42. Orlowski does not specifically teach the amount of the oil in the composition. However, one having ordinary skill in the art would have been able to determine the viscosity and specific gravity of oil used in the topical composition as well as the amount of oil according to its specific intended use, drug used and site of application.

Orlowski further differs from the instant claims insofar as it does not disclose the specific fraction of Gilsonite as claimed.

Forrest teaches Gilsonite can be made the basis for the production of a great variety of commercially useful products (col.3, lines 21-23), wherein the specific properties are so diverse that they can generally be utilized to the best advantage when the different products of Gilsonite are separated from one another by fractionation (col.4, lines 75-78 and 95) and purification (col.11, line 19). Forrest discloses the said properties include use as an emulsifying agent (col.12, line 113-114). Forrest teaches Gilsonite oil fractions with specific gravities of 0.870 (col.12, line 94), 0.927 and 0.933 (col.13, lines 21-26). Forrest teaches viscosities within the claimed range in the chart at (col.14, lines 75-85).

Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. See MPEP 2144.01, VII. Therefore, it would have been obvious to have used the purer form of the Gilsonite in

the aqueous emulsion composition of Orlowski motivated by the desire to use a product that has advantageous properties, i.e. emulsifying properties, when the product is purified as disclosed by Forrest.

In regards to the specific fraction of Gilsonite oil, Forrest teaches the fraction of Gilsonite oil having a viscosity of about 5 to about 1,000 cps at 25°C, and specific gravity of about 0.8 to 0.95. Therefore, the composition of Orlowski in view of Forrest meets the limitations claimed by claims 37-40, 42-43. Motivation to select Gilsonite oil having specific properties will logically flow from the cosmetic art based on the intended use of Gilsonite oil and composition incorporating it.

Response to Arguments

11. Applicant's arguments filed 06/22/02009 have been fully considered but they are not persuasive.

Applicant argues that there is such a clear indication and intention of claiming pharmaceutical compositions wherein the only ingredients are a bioactive agent for treating nail disease and Gilsonite oil, and that Gilsonite oil may serve as both the penetration enhancing agent and as carrier; but that other, merely optional, inactive and inconsequential additives may be included. Applicants further stated an intention of claiming formulations wherein the Gilsonite oil is the "major proportion ingredient."

In response to this argument, it is argued that the expression "consisting essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re*

Janakirama-Rao, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte,* 337 F 2d 870, 143 USPQ 256 (CCPA 1964). For the purposes of searching for and applying prior art, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" and is therefore, inclusive or open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03. Further, it has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

Applicants argue that Orlowski reference does not teach or suggest Gilsonite oil having beneficial properties, and does not teach discrete components of Gilsonite.

In response to this argument, it is argued that by Applicant's own admission, gilsonite is soluble in aliphatic, aromatic and chlorinated hydrocarbon solvents. CA '688 discloses Gilsonite in mineral oil carrier. By the broadest reasonable interpretation, the gilsonite in the presence of a hydrocarbon solvent (mineral oil) would inevitably lead to some if not all of the gilsonite solubilizing into mineral oil to form gilsonite oil. Further,

gilsonite oil is a component of gilsonite, therefore when gilsonite is dissolve in the hydrocarbon solvent, the gilsonite oil will be present. With regard to the amount of Gilsonite oil, one having ordinary skill in the art would have been able to determine such amount according to the intended use. In any event the reference disclosed 6.25% Gilsonite. The amount of Gilsonite in the composition can be adjusted by person of ordinary skill in the art according to the drug used, specific intended use and site of application.

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Applicants further argue that the amended claim 1 recites "Gilsonite oil is major proportion ingredient", and claim 41 recite "consisting of".

In response to this argument , it is argued that the specification does not provide definition to the term "major proportion", rather disclosed broad range of at least 0.1% and preferably from 1.0 to 80%. In absence of the definition of the claimed term "major proportion" and in light of the proportions and ranges disclosed by the specification, the amount 6.25% reads on the claimed ranges. Regarding claim 41, it has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

Applicants argue that Gilsonite disclosed by Orlowski when dissolve in mineral oil will provide low concentration of Gilsonite oil, 0.3%. Gilsonite was not disclosed to provide permeation enhancing effect. The art recognized that Gilsonite is chemically very complex, that there are many components to it, and that those components have diverse properties. Gilsonite is different from Gilsonite oil.

In response to this argument, applicants' attention is directed to the scope of the present claims that is directed to a composition, and all the elements of the composition are taught by the combined teachings of the prior art. According to applicants' calculation, Orlowski's composition will comprise 0.3% Gilsonite oil. One having ordinary skill in the art at the time of the invention would have been able to determine the amount of Gilsonite and mineral oil to add to the composition in order to achieve the desired amount of Gilsonite oil. Gilsonite oil is expected to act as permeation enhancer since compounds and their properties are inseparable. It is further argued that the prior art composition performed the same function of the present invention which is topical composition delivering active agents to the skin. One having ordinary skill in the art would have determined the desired amount of the oil in the composition according to the specific intended use, the property of the drug to be delivered and the specific site of application.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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